



state law,<sup>1</sup> the factual basis of all of their claims center on alleged misrepresentations concerning one of PacifiCare's Medicare insurance plans and alleged deficiencies by PacifiCare in providing Medicare coverage and benefits to Plaintiffs.

1.2 On June 25, 2007, PacifiCare removed this action from the Circuit Court of Bullock County, Alabama pursuant to 28 U.S.C. § 1331 & 1441(b) on grounds that Plaintiffs' claims herein all arise under the federal Medicare Act, 42 U.S.C. 1395w-21 – w-28, as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), and, accordingly, are preempted by federal law.

1.3 Plaintiffs' Motion to Remand (hereinafter the "Motion") complains that removal was improper. Plaintiffs' primary contention is that PacifiCare has not met its burden of demonstrating a substantial question of federal law or complete preemption under the Medicare Act necessary to establish federal subject matter jurisdiction. (Motion at ¶ 4). To support its allegation, Plaintiffs attempt to argue that Medicare statutory provisions do not provide for "complete preemption," relying on excerpts from federal case law and the Federal Register. (Motion at ¶¶ 5-6). As shown below, none of these grounds have merit, and Plaintiffs' Motion to Remand should be denied.

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<sup>1</sup> Plaintiffs' Complaint alleges the following causes of action against PacifiCare: (1) intentional, negligent or reckless misrepresentation (fraud); (2) suppression; (3) negligent, reckless or wanton hiring, training, monitoring and supervision; (4) conspiracy to defraud; (5) unjust enrichment/constructive trust; (6) negligence and wantonness; (7) breach of fiduciary duties; (8) intentional, wanton, reckless and/or negligent infliction of emotional distress; and (9) violation of the Alabama Deceptive Trade Practices Act. (See Plaintiffs' Complaint, pp. 6-14). In addition to compensatory and punitive damages, Plaintiffs seek to impose a constructive trust on payments and related fees paid by Plaintiffs to PacifiCare. (*Id.* at ¶ 40).

## II. ARGUMENT & AUTHORITIES

### A. Federal Jurisdiction Established

2.1 Plaintiffs contend that this Court lacks federal question jurisdiction because PacifiCare has failed to establish either that Plaintiffs seek relief under federal law or that their claims are preempted by federal law. (Plaintiffs' Memorandum of Law at pp. 6-9). While Plaintiffs are correct that federal jurisdiction normally is determined by the "well-pleaded complaint" rule, there is an exception "[w]hen a federal statute wholly displaces the state-law cause of action through complete preemption," thus permitting removal. *Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 8 (2003). In this case, regardless of how Plaintiffs have framed their Complaint, the crux of Plaintiffs' claims arise under federal law and are, in fact, completely preempted by federal law.

2.2 Specifically, Plaintiffs seek to recover damages from PacifiCare as alleged enrollees in a Medicare Advantage plan offered by PacifiCare in the form of its Secure Horizons Direct PFFS Plan (the "PFFS Plan"). As shown below, Plaintiffs' claims all relate to standards established under the Medicare Act for Medicare Advantage plans offered by private insurers. Plaintiffs' claims are thus superseded and completely preempted by federal law, namely 42 U.S.C. § 1395w-26(b)(3) (2006) (the Medicare Prescription Drug, Improvement, and Modernization Act or "MMA").

#### **1. *Statutory & Regulatory Preemption Under the Medicare Act/MMA.***

2.3 In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act. Under the MMA, Congress delegated the development of standards for marketing of Medicare Advantage plans and Prescription Drug Plans ("PDP's"), along with beneficiary enrollment, to the Department of Health & Human Services ("HHS"), a federal agency with specialized knowledge and long administrative

experience in the area. Congress included a preemption provision in the MMA that is even broader and more inclusive than the preemption provision in previous Medicare statutes. *Compare* 42 U.S.C. § 1395w-26(b)(3) (2006) *with* 42 U.S.C. § 1395w-26(b)(3) (2002). Previously, the Medicare Act preempted state laws and regulations to the extent that such laws and regulations were inconsistent with federal enactments. See 42 U.S.C. §1395w-26(b)(3). However, with the enactment of Section 232 of the MMA, Congress amended 42 U.S.C. §1395w-26(b)(3), effective 2003, to include a much broader preemption provision:

Relation to State laws. The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [Medicare Advantage] plans which are offered by [Medicare Advantage] organizations under this part.<sup>2</sup>

2.4 The legislative history of the MMA itself supports that Congress intended the Act's preemption to be broad in scope: "[t]he MA program is a Federal program operated under Federal rules. State laws do not, and should not apply...." H.R. Rep. No. 108-391, at 557 (2003), *as reprinted in* 2003 U.S.C.C.A.N. (108 Leg. His.) 1808, 1926. Accordingly, the new preemption provision significantly expanded the scope of federal preemption for claims related to Medicare Advantage plans. See 1395 C.F.R. §422.402. Congress acknowledged and appreciated the significance of a broader preemption provision: "[H]owever harsh preemption may seem to particular claimants, it comports with the purpose and structure of the MMA." 69 Fed. Reg. 46904 (August 3, 2004).

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<sup>2</sup> It is no coincidence that Section 232 is titled "Avoiding Duplicative State Regulation." This clause is also applicable to drug benefit providers. (42 U.S.C. §1395w-112(g)).

2.5 The Centers for Medicare and Medicaid Services (“CMS”), the division of HHS that operates the Medicare program, incorporated language in implementing regulations for Part D (the PDP provisions) that mirrors the statutory preemption language, declaring that “[t]he standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors.” 42 C.F.R. § 423.440(a) (2005). CMS understood the importance of the change:

[T]he [earlier] presumption was that a State law was not preempted if it did not conflict with a [Medicare managed care] requirement and did not fall into one of the four categories where preemption was presumed . . . [T]he MMA reversed this presumption and provided that *State laws are presumed to be preempted* unless they relate to licensure or solvency.

70 Fed. Reg., No. 18, p. 4319 (January 28, 2005) (emphasis added). CMS interprets MMA preemption to extend even to areas of *future* federal regulation: “Federal preemption is not exclusive to existing areas of Federal regulation. State standards, including those established through case law, are preempted to the extent that they specifically would regulate MA plans, with the exception of State licensing and solvency laws.” Medicare Managed Care Manual, Chapter 10, “20 – Extent of Federal Preemption with Respect to State Regulation of MA Plans.” Indeed, it points to the fact that “only those requirements that are directly related to becoming State licensed would be free from the possibility of Federal preemption.” *Id.*

2.6 Plaintiffs cite to one portion of the Federal Register in arguing that Congress did not intend for Medicare Act/MMA preemption to apply to state law claims. (Plaintiffs’ Memorandum of Law at p. 9). However, Plaintiffs’ reliance is wholly misplaced in light of additional language contained in Plaintiffs’ own Exhibit, yet not brought to the attention of the Court:

[It is] Congress' intent that the MA program, as a Federal program, operate under Federal rules, and ...the Conference Report of the MMA [makes] clear the Congress' intent to broaden the scope of preemption through its change to section [42 U.S.C. §1395w-26(b)(3)] of the Act.

70 Fed. Reg., No. 18, p. 4319 (January 28, 2005). Moreover, the excerpt from the *Comment* and *Response* that Plaintiffs rely upon in arguing against federal preemption notably fails to incorporate the remainder of that same *Response*:

The preemption in section 1860D-12(g) [42 C.F.R. 423.440(a)] of the Act is a preemption that operates only when CMS actually creates standards in the areas regulated. To the extent we do not create *any standards whatsoever* in a particular area, we do not believe preemption would be warranted.

70 Fed. Reg., No. 18, p. 4320 (January 28, 2005). As shown below, CMS not only created explicit standards governing Defendants' alleged conduct, but also actively enforces those standards. Accordingly, the Medicare Act/MMA completely preempts Plaintiffs' causes of action.

(a) **CMS Standards Expressly Govern Defendants' Alleged Conduct at the Core of Plaintiffs' Causes of Action.**

2.7 The factual claims giving rise to Plaintiffs' causes of action center around Defendants' alleged marketing, solicitation, and enrollment activities. (Plaintiffs' Complaint at pp. 3-6). The MMA directs CMS to establish regulations "relating to the approval of marketing material" and associated forms. 42 U.S.C. § 1395w-101(b)(1)(B)(vi) (2006). Under this mandate, CMS designed a detailed framework for the review and approval of advertisements and other promotions of plan sponsors like PacifiCare. See generally 42 C.F.R. § 423.50 (2005). Every form of marketing, including brochures, radio and television advertisements, internet materials, and direct presentations, is subject to this review by CMS. *Id.* at § 423.50(c). As part of this review, CMS reviews materials for misrepresentations or inaccurate statements,

rejecting any marketing materials having the potential to mislead beneficiaries. *Id.* at § 423.50(d)(4). There are also restrictions related to marketing activities, including misleading or confusing Medicare beneficiaries, misrepresenting the sponsor or plan, or soliciting Medicare beneficiaries door-to-door. *Id.* at § 423.50(f). Thus, any complaint over marketing materials, representations made in marketing a Medicare Advantage/PDP product, or marketing activities in general, fall within the purview of federal standards established under the Medicare Act/MMA.

2.8 Preemption also reaches any complaints by a beneficiary over enrollment in a Medicare Advantage/PDP plan. Congress charged HHS with establishing “a process for the enrollment” of beneficiaries in private Medicare Advantage/PDP plans. 42 U.S.C. § 1395w-101(b)(1)(A) (2006). In response, CMS promulgated regulations covering the enrollment process, including standard enrollment procedures, alternative enrollment mechanisms, and guidelines for processing enrollment requests. See *generally* 42 C.F.R. § 423.32 (2005). Among other things, these guidelines establish acceptable time periods available to Medicare Advantage/PDP sponsors for processing enrollment requests and sending notices to beneficiaries of enrollment decisions. *Id.* at 423.32(c)-(d). Throughout, the regulations envision an active role for CMS in the oversight and monitoring of the enrollment process. See, e.g., *Id.* at § 423.32(c) (providing for processing of enrollment requests “in accordance with CMS enrollment guidelines”); *Id.* at § 423.32(d) (notice must be provided “in a format and manner specified by CMS”). The facts forming the basis of Plaintiffs’ claims focus on the alleged marketing, solicitation, and enrollment activities of Defendants. (Plaintiffs’ Complaint at pp. 3-6). Because existing CMS standards effectively govern Defendants’ alleged conduct, Plaintiffs’ causes of action are preempted by federal law.

(b) **CMS Actively Regulates and Enforces Marketing and Enrollment Activities Related to Medicare Advantage Plans.**

2.9 CMS—not the State of Alabama—plays the lead role in vigorously enforcing the marketing and enrollment activities of Medicare Advantage plan providers, including PacifiCare. Plaintiffs direct the Court’s attention to two Bulletins issued by Walter Bell, the Commissioner of Insurance for the State of Alabama, Department of Insurance (the “Bulletins”), dated February 16, 2006 and June 8, 2007. Plaintiffs mistakenly assume that the Bulletins’ language means that CMS is redirecting all claims regarding Medicare marketing to the Alabama Department of Insurance, thus concluding that “the intent of the preemption section of the [Medicare Act/MMA] was not to cover marketing activity of Medicare Advantage products.” (Plaintiffs’ Memorandum of Law at p. 11). In essence, Plaintiffs contend that because CMS *allegedly* does not monitor or regulate the marketing practices of Medicare in Alabama, including the sale of the PFFS plans at issue in this case, federal Medicare preemption does not apply to Plaintiffs’ claims.

2.10 Plaintiffs’ argument is specious for several reasons. First, the Bulletins issued by the Alabama Department of Insurance do not have the force or effect of law, nor does the agency have or even purport to have the authority to interpret federal law and its application.

2.11 Second, CMS recently has made very clear that it retains the authority to monitor, investigate, and resolve issues pertaining to the marketing of Medicare plans. Specifically, CMS recently reaffirmed the role of federal regulation in such marketing efforts. On May 25, 2007, the Director of the Center for Beneficiary Choices, a department of the CMS, issued a Memorandum to all Medicare Advantage PFFS plans

setting forth the federal expectations and requirements for proper marketing practices (hereafter, the “CMS Memorandum”, attached hereto as “Exhibit A”). The purpose of the CMS Memorandum is to detail marketing processes and best practices with which all PFFS plan providers—including PacifiCare—must comply. (Exhibit A, ¶ 2). When read in conjunction with applicable federal statutes, regulations, and Medicare marketing and enrollment rules, it is clear that marketing practices by Medicare PFFS plans are controlled by federal law, which thus necessarily preempts state law claims related to marketing and enrollment practices.

2.12 In fact, as the CMS Memorandum details, the marketing processes that may be used require prior authorization from and substantial involvement of CMS. For example, Medicare Advantage organizations offering PFFS plans must provide CMS Regional Managers with information on a monthly basis regarding any planned PFFS marketing and sales events prior to such events taking place. (*Id.* at ¶ 3). All advertisements and enrollment materials related to PFFS plans must now include a specific CMS-created disclaimer, detailing how PFFS plans differ from Medicare Supplement plans. (*Id.* at ¶ 5). Moreover, CMS clearly mandates that Medicare Advantage organizations immediately discontinue the use of marketing materials or cease giving presentations which imply that PFFS plans function as a Medicare Supplement—an alleged practice specifically complained of by Plaintiffs. (Plaintiffs’ Complaint at ¶¶ 13-14). Any revised marketing or advertising materials must be submitted to CMS for processing and certification. (Exhibit A, ¶ 4). To emphasize the federal authority by which CMS intends to enforce such marketing practices and policies, the CMS Memorandum includes the following language:

*CMS remains vigilant in protecting Medicare beneficiaries. We will focus compliance oversight activities on ensuring the provision of information to beneficiaries accurately represents the access, network, and payment features of PFFS plans generally, and each organization's specific plan. CMS has the authority to impose intermediate sanctions and penalties including the freezing of all marketing and enrollment, civil money penalties and other enforcement actions as described in Federal regulations at 42 C.F.R. §422 Subpart K and O, against organizations violating Medicare program requirements. We are closely monitoring beneficiary complaints and other marketplace-based information to determine whether compliance and/or enforcement actions are warranted.*

(*Id.* at ¶ 20) (emphasis added). Without a doubt, CMS has been and remains heavily involved in setting applicable legal standards, and then monitoring, investigating, and controlling marketing activities by Medicare PFFS plans.

2.13 Plaintiffs' allegations in this lawsuit squarely fit into the marketing practices for which CMS sets the legal standards. Plaintiffs' primary contentions in this suit relate to alleged wrongful and deceptive marketing practices by PacifiCare's agents in the sale of Secure Horizons, a PFFS plan. (See Plaintiffs' Complaint, pp. 6-14). The federal regulations cited elsewhere in this Response and the CMS Memorandum specifically indicate that CMS not only has authority to set appropriate legal standards and govern marketing conduct, but that CMS has exercised that authority by requiring organizations offering PFFS plans to comply with its standards and processes. (Exhibit A, ¶ 2). Under the clear terms of the CMS Memorandum, any argument by Plaintiffs that CMS is somehow redirecting or otherwise deflecting the regulation of PFFS marketing practices to the states is clearly erroneous.

2.14 In summary, there is a comprehensive federal statutory and regulatory framework addressing marketing and enrollment procedures under all Medicare Advantage/PDP plans. Moreover, as evidenced by the recent CMS Memorandum, it is

abundantly clear that marketing practices by Medicare PFFS plans are controlled by federal law and actively enforced by CMS—not state governments. Therefore all claims, whether couched as state law claims or otherwise, related to Defendants’ alleged marketing, solicitation, and enrollment of Plaintiffs are completely preempted under the broad provisions of the federal Medicare Act, 42 U.S.C. §1395w-21-w28, as amended by the MMA in 2003.

## **2. Judicial Application of Preemption Requirements.**

2.15 Congress has the authority to define the extent to which federal statutes preempt state law. See *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95-98 (1982). Where, as here, Congress chooses to explicitly describe a federal law’s preemptive reach, “the court’s task is an easy one,” namely that of enforcing Congressional intent. *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990); *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

2.16 Plaintiffs contend that it is “well established” that the Medicare Act does not provide for complete preemption, relying solely on two cases – *Burke v Humana Ins. Co.*, 1995 WL 841678 (M.D. Ala.) (unpublished) and *Grace v. Interstate Life & Accident Ins. Co.*, 916 F. Supp. 1185 (M.D. Ala. 1996). However, Plaintiffs fail to inform the Court that both of these cases were decided *prior* to the enactment of the MMA and its admittedly broader preemption provision in 2003. As such, neither case is instructive with respect to the newer and broader MMA preemption standard.<sup>3</sup> Moreover, even under the older, more narrow Medicare preemption standard, Courts held that preemption applies to claims that are “inextricably intertwined” with claims for past or

<sup>3</sup> In any event, the *Burke* Court specifically noted that, unlike here, the defendants had failed to point to any congressional intent for preemption under the Medicare Act. *Burke*, 1995 WL 841678 at \*3. In *Grace*, the defendants did not even allege that the Plaintiff’s claims were preempted. *Grace*, 916 F. Supp. at 1191.

future Medicare benefits. See, e.g., *Heckler v. Ringer*, 466 U.S. 602, 606 (1984); *Midland Psychiatric Associates, Inc. v. United States*, 145 F.3d 1000 (8<sup>th</sup> Cir. 1998); *Bodimetric Health Services, Inc. v. Aetna Life & Casualty*, 903 F.2d 480 (7<sup>th</sup> Cir. 1990).

2.17 With the passage of the MMA, Congress declared that state standards concerning benefits and other activities governed by Medicare standards are *presumptively* preempted. See 70 Fed. Reg., No. 18, p. 4319 (January 28, 2005). Courts that have considered the preemptive effect of the 2003 MMA amendment on claims against Medicare managed care contractors—like PacifiCare—have found complete preemption of any state law claim, other than those relating to State licensing and solvency requirements. See, e.g., *First Med. Health Plan, Inc. v. Vega*, 406 F. Supp. 2d 150, 154 (D.P.R. 2005) (“Congress made clear its intent to expressly preempt the application of any state law to Medicare Advantage programs, other than laws related to licensing or plan solvency.”); *Uhm v. Humana, Inc.*, 2006 WL 1587443 (W.D. Wash. June 2, 2006) (holding that claims of consumer protection and fraud against a PDP were preempted by the MMA) (copy attached as “Exhibit B”). Neither the Eleventh Circuit nor the federal courts in Alabama have addressed preemption under the new MMA provision. Plaintiffs concede, however, that complete preemption exists for claims arising under the Employee Retirement Income Security Act (“ERISA”) (Plaintiffs’ Memorandum of Law at p. 7). Despite Plaintiffs’ argument to the contrary, the broad preemption language used in the MMA closely follows ERISA’s preemption provision.<sup>4</sup> Accordingly, the well-developed precedent regarding complete preemption of state law

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<sup>4</sup> ERISA’s preemption provision provides, with certain narrow exceptions, that ERISA’s provisions “supersede any and all state laws insofar as they may now or hereafter relate to any employee benefit plan....[covered by ERISA].” 29 U.S.C. § 1144(a). This “superseding” language parallels the broad preemption language in the MMA.

claims that are governed by ERISA provides additional support for broad MMA preemption. See *Aetna Health, Inc. v. Davila*, 542 U.S. 200 (2004).

2.18 Federal preemption applies not only to state regulation but also to private lawsuits under state law. Thus, if a plaintiff's private state law causes of action relate to a field covered by federal regulations, they are preempted. See *Law v. Gen. Motors Corp.*, 114 F.3d 908 (9th Cir. 1997). Courts specifically have found that the broad scope of MMA preemption encompasses state contract and tort remedies. See *Uhm*, 2006 WL 1587443 at \*3.

2.19 For example, in *Uhm v. Humana, Inc.*, Plaintiffs brought various state-law claims against sponsors of a Medicare Part D Prescription Drug Plan. See 2006 WL 1587443 at \*1. Plaintiffs claimed that they relied on defendants' advertising materials in choosing their PDP. See *Id.* The *Uhm* Plaintiffs also claimed that the PDP defendants represented to plaintiffs that they would receive drug benefits beginning on January 1, 2006. See *Id.* Plaintiffs claimed they were not covered on January 1, 2006, as the PDP defendants promised, and as a result, Plaintiffs were forced to purchase their prescription drugs out-of-pocket at retail prices. See *Id.* Plaintiffs asserted state law claims for breach of contract, violation of state consumer protection statutes, unjust enrichment, fraud, and fraud in the inducement. See *Id.* at \*2. The PDP defendants moved to dismiss for failure to state a claim, arguing that the MMA regulations governing marketing materials expressly preempted plaintiffs' state law claims based on allegedly fraudulent marketing or misrepresentation of the PDP's benefits. See *Id.* The Court granted the defendants' motion, holding the "structure and purpose of the Medicare statutes confirm Congress' intent to preempt most state law with federal standards." *Id.* at \*4. Plaintiffs' claims in the present suit rely on similar allegations of

misrepresentation in marketing and even assert some identical causes of action as set forth in *Uhm*. The Court should therefore accept and rely on the *Uhm* Court's persuasive reasoning.

### **3. *Plaintiffs' Claims are Preempted.***

2.20 The Plaintiffs herein assert causes of action for intentional, negligent or reckless misrepresentation (fraud); suppression; negligent, reckless or wanton hiring, training, monitoring and supervision; conspiracy to defraud; unjust enrichment/constructive trust; negligence and wantonness; breach of fiduciary duties; intentional, wanton, reckless and/or negligent infliction of emotional distress; and violation of the Alabama Deceptive Trade Practices Act. (See Plaintiffs' Complaint, pp. 6-14). While ostensibly state law claims, if the gravamen of Plaintiffs' allegations trigger federal preemption, the action may be removed to federal court. See *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58 (1987) (removal of "state" common law contract and tort claims proper when those claims were preempted by ERISA and properly recharacterized as federal in nature).

2.21 The pertinent factual allegations underlying Plaintiffs' causes of action are as follows:

- (1) Plaintiffs were enrolled in a *Medicare Advantage plan* sponsored by Secure Horizons Direct and administered by PacifiCare, also known as a "Private Fee for Service" plan (Plaintiffs' Complaint at ¶ 11, 15);
- (2) Defendants contacted Plaintiffs, former *Medicare recipients* in Bullock County, Alabama, and misrepresented that "Secure Horizons provided extra benefits or extra help for *Medicare*," or was "extra *Medicare*," and misrepresented that "Plaintiffs could still use their *Medicare card*." (*Id.* at ¶¶ 10-14);
- (3) Plaintiffs' benefits and healthcare *coverage through Medicare* was drastically *reduced*, and medical services previously provided under

*Medicare were denied under PacifiCare's Secure Horizons plan, resulting in physical injury, emotional distress, and large medical bills (Id. at ¶¶ 16-17); and*

- (4) Defendants failed to disclose that "by enrolling in the Secure Horizons plan, the Plaintiffs would be *disenrolled from Medicare* and/or taken out of *Medicare* and/or would *no longer be eligible for Medicare* and/or would receive the same benefits." Plaintiffs "would not have enrolled" in the plan if they had known these facts, and aside from damages, Plaintiffs seek a constructive trust on "payments and related fees that Defendants wrongfully and improperly obtained." (*Id.* at ¶¶ 26-27, 40).

Simply put, Plaintiffs assert that Defendants misrepresented the terms of the Secure Horizons plan as it related to Medicare coverage; failed to inform Plaintiffs that they were being dis-enrolled from regular Medicare coverage; reduced Plaintiffs' Medicare coverage; diverted Plaintiffs' Medicare premiums to PacifiCare; and denied Plaintiffs' medical claims that otherwise would have been covered under Medicare.

2.22 All of Plaintiffs' claims are completely preempted by the Medicare Act/MMA for several independent reasons. First, Plaintiffs' primary allegation is one of fraud based on alleged misrepresentation of the benefits, requirements, terms, and conditions of enrollment in PacifiCare's PFFS Plan. (See, e.g., Plaintiffs' Complaint at ¶¶ 14-15, 19-24, 26, 35-37). This allegation directly implicates standards set forth under the Medicare Act/MMA related to enrollment, including Pacificare's marketing efforts and materials. 42 U.S.C. § 1395w-101(b)(1)(A), (B)(vi) (2006); 42 C.F.R. § 423.50 (2005).

2.23 Second, Plaintiffs complain that their benefits and coverage were reduced, previously covered medical care was denied to them under PacifiCare's Medicare Advantage plan, and they "have incurred medical expenses that they should not owe" (in other words, that PacifiCare denied them Medicare benefits pursuant to its PFFS Medicare Advantage plan). (Plaintiffs' Complaint at ¶¶ 16-17, 24). Plaintiffs attempt to

convince this Court that they are not complaining of a “coverage determination” or an “unpaid claim” by Medicare or PacifiCare. (Plaintiffs’ Memorandum of Law at p. 12). To support this contention, Plaintiffs are careful to point out that they incurred medical bills while visiting doctors and healthcare providers “not a part of the PacifiCare network.” (Plaintiffs’ Memorandum of Law at p. 5). At the time of these visits, however, Plaintiffs were in fact enrolled in PacifiCare’s Medicare Advantage plan. Otherwise, according to Plaintiffs, their Medicare claims would not have been denied (See Plaintiffs’ Complaint at ¶ 16). PacifiCare’s alleged failure to cover Plaintiffs’ medical expenses at non-network providers directly implicates a coverage and/or denial of benefits issue under its Medicare Advantage plan. This fact is supported by allegations in Plaintiff’s own Complaint, which expressly details how they “have been forced to pay out-of-pocket for prescription drugs and other medical equipment and supplies which would have previously been covered partially or in full by Medicare.” (Plaintiffs’ Complaint at ¶ 16).

2.24 Clearly, Plaintiffs’ allegations relate not only to the extent of benefits represented by PacifiCare, but also to those medical services Plaintiffs received that PacifiCare allegedly denied under its Medicare Advantage plan. Thus, no matter how artfully phrased, the core of Plaintiffs’ complaints relate to coverage determinations by PacifiCare, as regulated by the Medicare Act/MMA. These claims are preempted under the MMA’s broad preemption provision. Even under the narrow Medicare preemption standard that existed prior to 2003, these claims still would be preempted because they are “inextricably intertwined” with claims for past or future Medicare benefits. See, e.g., *Heckler v. Ringer*, 466 U.S. 602, 606 (1984); *Midland Psychiatric Associates, Inc. v. United States*, 145 F.3d 1000 (8<sup>th</sup> Cir. 1998); *Bodimetric Health Services, Inc. v. Aetna Life & Casualty*, 903 F.2d 480 (7<sup>th</sup> Cir. 1990).

2.25 Third, Plaintiffs' allegations of reduced benefits, diversion of premiums, and denial of medical care implicate the grievance and appeals procedures established under the Medicare Act/MMA. 42 C.F.R. §§ 423.560, 423.566, 423.568, 423.570, 423.580-90, 423.600-04, 423.610, 423.630 (2005). Plaintiffs' misrepresentation claims against PacifiCare assert, in essence, that certain promises or representations related to benefits and medical coverage proved untrue. Accordingly, as in *Uhm*, Plaintiffs' fraud, fraudulent inducement, and consumer protection claims are preempted by MMA marketing regulations. See *Uhm*, 2006 WL 1587443 at \*2-3. Moreover, like the plaintiffs in *Uhm*, Plaintiffs' allegations in this case regarding denied medical services and improperly incurred medical expenses directly implicate the grievance and appeals process under the Medicare Act/MMA. See *Uhm*, 2006 WL 1587443 at \*3.

2.26 Plaintiffs' claims, which all relate to PacifiCare's marketing efforts and/or materials, the extent of benefits or coverage promised and/or provided to Plaintiffs, and Medicare-related grievance and appeals procedures, are completely preempted under the Medicare Act/MMA. Therefore, this Court has original jurisdiction pursuant to 28 U.S.C. § 1331, and Plaintiffs' Motion to Remand should be denied. To the extent that any of Plaintiffs' state law claims survive preemption, this Court should exercise supplemental or pendent jurisdiction and try them together with the federal claims.

2.27 Plaintiffs contend that because the Medicare Act/MMA does not displace their claims with a cause of action, they will be left without a remedy if the Court holds that preemption exists. (Plaintiffs' Memorandum of Law at pp. 11-12). However, as the *Uhm* Court held: "[h]owever harsh preemption may seem to particular claimants, it is consistent with the structure and purpose of the MMA....the structure and purpose of the Medicare statutes confirm Congress's intent to preempt most state law with federal

standards.” *Uhm*, 2006 WL 1587443 \*4. The harshness of preemption in this instance is mediated by the availability of administrative remedies; indeed, Plaintiffs should be *required* to exhaust their administrative remedies before seeking judicial relief under controlling regulations. See 42 C.F.R. §§ 422.560-422.612. Although Plaintiffs mistakenly argue that preemption must not apply in this case since the MMA creates no private causes of action, Plaintiffs are not left without remedial procedures under the statutory framework promulgated by Congress. For example, Plaintiffs allege that they should not have been enrolled in the PacifiCare PFFS Plan, and that their premiums should be returned. Plaintiffs can use administrative processes to seek disenrollment and a return of their premiums. See *Id.* § 423.564. Plaintiffs have the opportunity to obtain a remedy directly from PacifiCare, and if they remain dissatisfied, they can then seek relief from a neutral third-party, and if they continue to remain dissatisfied, they can seek relief from the federal court system. See *Id.* §§ 422.560-422.612. Exhaustion of these administrative remedies is a jurisdictional prerequisite to the relief sought by Plaintiffs.

**WHEREFORE**, PacifiCare Life & Health Insurance Company and United HealthCare Services, Inc. respectfully request that the Court deny Plaintiffs’ Motion to Remand, and for any other relief to which it is entitled.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on July 30, 2007, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

Robert G. Methvin, Jr.  
J. Matthew Stephens  
Rodney E. Miller  
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and I hereby certify that I have mailed by United States Postal Service the document to the following non-CM/ECF participants:

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s/ William C. McGowin  
\_\_\_\_\_  
Of Counsel

# **Exhibit A**

Department of Health & Human Services  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850



CENTER FOR BENEFICIARY CHOICES

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DATE: May 25, 2007

TO: Medicare Advantage Private Fee-for-Service (PFFS)  
Plans

FROM: Abby L. Block  
Director, Center for Beneficiary Choices (CBC)

SUBJECT: Ensuring Beneficiary Understanding of Private Fee-for-Service Plans, Actions  
and Best Practices

Private Fee-For-Service (PFFS) plans are a growing segment of the Medicare Advantage (MA) program. These plans differ from other MA products. As more PFFS plans become available, CMS began to work with beneficiaries, providers and MA organizations to provide education and information describing this plan option.

As described in the 2008 Call Letter, CMS is providing additional model documents and requiring new outreach processes to ensure beneficiaries and providers are informed about the distinctive features of Medicare PFFS plans. MA organizations offering PFFS plans are strongly encouraged to implement these new elements and practices as quickly as possible. Several of these must be implemented immediately as indicated in the discussion below. All PFFS organizations must have these processes in place prior to marketing CY 2008 PFFS plans.

### **PFFS Marketing Processes**

1. Sales presentation schedules

MA organizations offering PFFS plans must provide their CMS Regional Office Plan Manager with listings of planned PFFS marketing and sales events, using the attached spreadsheet (refer to **Attachment 1**). Data for events conducted by both employed and contracted sales representatives is required. Beginning June 20, 2007, by the 20<sup>th</sup> of each month you must provide information for all events scheduled for the following month. The first report is due by June 20, 2007 and must list all events planned for July 2007. The Regional Office Plan Manager must be notified of updates to the schedule as appropriate. In addition, CMS encourages PFFS plans to maintain an up-to-date schedule of sales events on the plan's website. Each submitted spreadsheet must be accompanied by a signed and dated attestation from the organization's Medicare program vice president or director, attesting to

best knowledge, information and belief, that the information provided to CMS is accurate as of the date submitted.

2. Prohibition against implying PFFS plans function as Medicare supplements

MA organizations offering PFFS plans are prohibited from using any materials or making any presentations that imply PFFS plans function as Medicare supplement plans or use terms such as “Medicare Supplement replacement”. MA organizations may not describe PFFS plans as plans that cover expenses that Original Medicare does not cover nor as plans that offer Medicare supplemental benefits. It would be permissible, however, for PFFS plans to clarify that the plan does not pay after Medicare pays its share, but rather, it pays instead of Medicare and the beneficiary pays any applicable cost-share or co-pay. Immediately discontinue use of any materials not meeting this requirement. Revised materials may be submitted through the File and Use Certification process.

3. PFFS marketing material disclaimer

MA organizations offering PFFS plans are required to prominently display the following disclaimer in all advertisements and enrollment related materials:

*A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. Your doctor or hospital must agree to accept the plan's terms and conditions prior to providing healthcare services to you, with the exception of emergencies. If your doctor or hospital does not agree to accept our payment terms and conditions, they may not provide healthcare services to you, except in emergencies. Providers can find the plan's terms and conditions on our website at: [insert link to PFFS terms and conditions].*

This language is also required in sales presentations in public venues and private meetings with beneficiaries. Any statement indicating that enrollees may see any provider must also include, the phrase “. . . who agrees to accept our terms and conditions of payment.” CMS approval of this language prior to use is not required. Plans should begin using the disclaimer language immediately in sales presentations and as soon as possible in printed materials.

4. Beneficiary and provider leaflet

All MA organizations must provide enrollees with a complete description of plan rules, including detailed information on a provider's choice whether to accept plan terms and conditions of payment. A model document that beneficiaries may show their health care providers has been developed for this purpose (refer to **Attachment 2**). The model is a two-sided leaflet, with information for beneficiaries on one side and information for providers on the reverse.

The leaflet must be included in all enrollment kits that prospective enrollees receive. This leaflet must be available on your website for beneficiaries who enroll online. CMS will also post a model leaflet on the Medicare.gov website. It may be helpful to provide several copies to each beneficiary so that they can give copies to their health care providers. The leaflet must be implemented as quickly as possible and submitted to CMS using the File and Use Certification process prior to marketing CY 2008 PFFS plans.

5. Outbound education and verification calls

All MA organizations offering PFFS plans are required to conduct outbound education and verification calls to ensure beneficiaries requesting enrollment understand the plan rules. It is important for your sales staff to obtain from the beneficiary the verification phone number and provide a description of the enrollment verification process to the beneficiary during the application process. Your approved enrollment application form must accommodate this requirement.

Outbound calls mean that calls are made to the beneficiary after the sale has occurred. Calls cannot be made at the point of sale. You must ensure that the verification calls made to beneficiaries who request enrollment through sales agents are not made directly by those sales agents and also that the sales agents are not with the beneficiaries at the time of the verification call. You will be required to conduct these calls for all new enrollments except enrollments into employer or union sponsored PFFS plans or switches from one PFFS plan to another PFFS plan offered by the same MA organization. A model script has been developed for this purpose (refer to **Attachment 3**). You may continue to use existing scripts provided the information in the attached model document is conveyed during verification calls. Your script needs to be submitted to CMS through the normal process for approval.

Three documented attempts to contact the applicant by telephone within 10 calendar days of receiving the application are required. If you are unable to successfully complete the verification after the first attempt, you must send the applicant the model education letter (refer to **Attachment 4**). You must provide this letter in addition to any required enrollment notice, such as enrollment acknowledgement and confirmation letters (refer to **Attachments 5 and 6**, respectively). After the model education letter has been sent, you must make and document at least two additional attempts to successfully complete the verification. Be certain to document verification activities as they will be subject to compliance audit by CMS or its contractors.

Immediate implementation of this process is recommended; however, you must have this process in place before marketing CY 2008 PFFS plans.

6. PFFS Enrollment Processing

The special processes and marketing practices described in this memo are designed to ensure new enrollees have all required information to understand the plan in which they are enrolling. Conducting this outreach and education does not change the requirements to which all MA organizations must adhere for processing MA enrollment requests. Please refer to the CMS MA Eligibility, Enrollment and Disenrollment Guidance, available at [www.cms.hhs.gov](http://www.cms.hhs.gov), for more information.

## **Best Practices**

1. PFFS-specific sales presentation language

Model language is provided to incorporate into sales presentations describing the special aspects of PFFS plans which differ from supplements and other MA plans (refer to **Attachment 7**). You may submit this language with revised sales presentations using the normal marketing submission process.

2. Participation in HEDIS and HOS

We encourage organizations offering PFFS plans to participate in HEDIS and the Health Outcomes Survey (HOS) in 2008. Submitting this information helps CMS calculate and display much of the comparative information featured in the Medicare Options Compare tool. This tool is used by beneficiaries and their representatives in making informed health care decisions. You will receive more information regarding how to take advantage of this opportunity in the future.

3. Provider education plan

You are required to have staff available to assist providers with questions concerning plan payment and payment accuracy. Please refer to the document entitled "MA Payment Guide for Out of Network Payments" available on our web site at <http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats>. In addition, we encourage PFFS plans to develop provider relations strategies to encourage a wide range of providers to accept PFFS enrollees. We suggest PFFS plans develop a provider education process and educational materials that includes establishing relationships with and educating providers in the PFFS plan service area.

To further assist providers, we have posted on the CMS website all the PFFS plans' contact information concerning PFFS plan terms and conditions of payment. Also, PFFS plans are required to make their terms and conditions of payment reasonably available to U.S. providers. A provider has reasonable access to a plan's terms and conditions of payment if the plan makes this information easily accessible through electronic mail, fax, telephone, or the plan website. The contact information for all PFFS contracts is posted on <http://www.cms.hhs.gov/PrivateFeeforServicePlans/>. Updates to the contact information will be made on a monthly basis.

New fields will be added in HPMS to allow PFFS plans to provide their plan terms and conditions of payment contact information for providers, which will be used to update the CMS website. CMS will inform all PFFS plans when the information may be entered in HPMS.

You should consider sending a provider educational material packet to those providers listed on enrollment requests (if provided), and those who call or bill for services that have not already received a packet. The contents of the provider education material packet could include the updated CMS provider education letter (refer to **Attachment 8**), the provider educational information in the document described above (refer to **Attachment 2**), and the terms and conditions of payment. We may require that organizations offering PFFS plans having documented provider access problems provide data about provider education and outreach efforts.

As stated in the 2008 Call Letter, CMS remains vigilant in protecting Medicare beneficiaries. We will focus compliance oversight activities on ensuring the provision of information to beneficiaries accurately represents the access, network, and payment features of PFFS plans generally, and each organization's specific plan. CMS has the authority to impose intermediate sanctions and penalties including the freezing of all marketing and enrollment, civil money penalties and other enforcement actions as described in Federal regulations at 42 C.F.R. §422 Subpart K and O, against organizations violating Medicare program requirements. We are closely monitoring beneficiary complaints and other marketplace-based information to determine whether compliance and/or enforcement actions are warranted.

We appreciate your cooperation in implementing these important steps. Please notify your Regional Office Plan Manager as you implement each of the items described above. You may direct any questions concerning these requirements to your Regional Office Plan Manager.

# **Exhibit B**

Westlaw.

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(Cite as: Not Reported in F.Supp.2d)

**C**Uhm v. Humana, Inc.  
W.D.Wash.,2006.United States District Court, W.D. Washington,  
at Seattle.Do Sung UHM and Eun Sook Uhm, a married  
couple, individually, and for all others similarly  
situated, Plaintiffs,

v.

HUMANA, INC., a Delaware corporation, Humana  
Medical Plan, Inc., a Florida corporation, Humana  
Health Plan, Inc., a Kentucky corporation, all d/b/a  
Humana, Defendants.

No. C06-0185-RSM.

June 2, 2006.

Joseph Andrew Grube, Ricci Grube Aita, Scott C.  
Breneman, Breneman Law Firm, Seattle, WA, for  
Plaintiffs.Arissa M. Peterson, Mary Rebecca Knack, Williams,  
Kastner & Gibbs, Seattle, WA, Brian D. Boyle,  
O'Melveny & Myers, Washington, DC, for  
Defendants.ORDER GRANTING DEFENDANTS' MOTION  
TO DISMISS FOR FAILURE TO STATE A CLAIM  
RICARDO S. MARTINEZ, District Judge.\*1 This matter comes before the Court on defendant  
Humana Health Plan, Inc.'s Motion to Dismiss for  
Failure to State a Claim. (Dkt.# 9-1). Remaining  
defendant Humana, Inc. has joined in the motion to  
dismiss.<sup>FNI</sup> (Dkt. # 24). Oral argument was held on  
May 26, 2006, and the matter has been fully  
considered. For the reasons set forth below,  
defendants' motion shall be granted.FNI. On April 18, 2006, plaintiffs filed an  
objection to Humana, Inc.'s joinder in  
Humana Health Plan's motion to dismiss.  
(Dkt.# 25). However, the same legal  
arguments apply to Humana, Inc. and  
Humana Health Plan, Inc. in this case, and  
the Court finds that Humana Inc.'s joinder in  
the motion to dismiss is proper.In this action, plaintiff brought various state-law  
claims against defendants, who are sponsors of aMedicare Part D (" Part D" or " Drug Benefit" )  
prescription drug plan (" PDP" ). Defendants argue  
that the Medicare Prescription Drug, Improvement,  
and Modernization Act of 2003 (" MMA" ) (Pub.L.  
No. 108-173, 117 Stat.2066 (codified in scattered  
sections of 42 U.S.C)), expressly preempts state law  
with respect to any aspect of the Drug Benefit for  
which there are federal standards. Defendants assert  
that plaintiffs' claims are preempted by federal law  
because there are federal standards which govern the  
subject matter of each of plaintiffs' claims.  
Defendants further argue that plaintiffs may not seek  
judicial review of their claims until they have  
exhausted the MMA-established administrative  
remedies for coverage determinations and other  
grievances.Plaintiffs respond that Congress did not intend for the  
MMA's express preemption language to preempt  
state tort and contract claims. Plaintiffs further argue  
that their claims do not " arise under" the Medicare  
Act, and that the claims are not preempted, according  
to the rule set out in Heckler v. Ringer, 466 U.S. 602,  
615, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984).  
Plaintiffs also argue that the doctrine of exhaustion of  
administrative remedies is not applicable to plaintiffs  
because they do not seek a coverage determination  
and because the grievance procedure for non-  
coverage-determination grievances would be futile.

## DISCUSSION

*A. Background*Plaintiffs are senior citizens who wished to enroll in  
the new Medicare Part D prescription drug benefit  
program created by the MMA. (Dkt. # 1-1 at 2). The  
Drug Benefit is administered by the Centers for  
Medicare and Medicaid Services (" CMS" ), a federal  
agency. (Dkt. # 9-1 at 4).Plaintiffs allege that they chose defendant Humana's  
prescription drug plan (" PDP" ) from among many  
PDP options. (Dkt. # 1-1 at 7). In choosing  
defendants' plan, plaintiffs relied on defendants'  
advertising materials. (Dkt. # 1-1 at 8). Plaintiffs then  
completed the Humana PDP enrollment form. (Dkt. #  
1-1 at 7). Defendants represented to plaintiffs that  
they would receive the Drug Benefit beginning on

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January 1, 2006. (Dkt. # 1-1 at 7). Defendants began charging plaintiffs a monthly premium in January, 2006. (Dkt. # 1-1 at 4). Defendants' PDP required that enrollees use a mail-order form to obtain their prescription drugs. (Dkt. # 1-1 at 9). Between mid-December and early February 2006, plaintiffs made numerous requests for Drug Benefit order forms and instructions, but defendants failed to provide them to plaintiffs. (Dkt. # 1-1 at 9-10). Plaintiffs were forced to purchase their prescription drugs out-of-pocket at retail prices. (Dkt. # 1-1 at 10).

\*2 Plaintiffs commenced this action on February 2, 2006. (Dkt. # 1-1 at 1). They claim breach of contract, violation of state consumer protection statutes, unjust enrichment, fraud, and fraud in the inducement. (Dkt. # 1-1 at 14-17). Plaintiffs purport to bring this action as a class action under F.R.C.P. 23. (Dkt. # 1-1 at 11-13).

Defendants have moved to dismiss for failure to state a claim pursuant to F.R.C.P. 12(b)(6).

#### *B. Motion to Dismiss Standard*

In the context of a Rule 12(b)(6) motion to dismiss for failure to state a claim upon which relief may be granted, the Court must (1) construe the complaint in the light most favorable to plaintiff; (2) accept all well-pleaded factual allegations as true; and (3) determine whether the plaintiff can prove any set of facts to support a claim that would merit relief. *See, Cahill v. Liberty Mutual Insurance Company*, 80 F.3d 336, 337-38 (9th Cir.1996).

#### *C. Preemption*

Defendants argue that the MMA expressly preempts plaintiffs' state law claims. When interpreting an express preemption clause, the Court first focuses on the plain meaning of the statutory language, which provides the best evidence of congressional intent. CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664, 113 S.Ct. 1732, 123 L.Ed.2d 387 (1993). The relevant statutory language is found in 42 U.S.C. § 1395w-26(b)(3) (2006), which provides:

The standards established under this part shall supersede any state law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [Medicare Part C managed care] plans which are offered by [Medicare managed care] organizations under this part.

The clause applies to Medicare Part D Drug Benefit providers pursuant to 42 U.S.C. § 1395w-112(g) (2006). The language of the MMA preemption clause is clear: if Part D establishes standards that cover plaintiffs' claims, then those standards supersede state law, and plaintiffs' state law claims are preempted.<sup>FN2</sup>

FN2. Plaintiffs argue that their claims do not "arise under" the Medicare Act and are therefore not preempted by federal standards pursuant to the rule in *Heckler v. Ringer*. However, the *Heckler* standard does not apply here. In that case, the court interpreted a section of the Medicare Act which made judicial review possible only after the exhaustion of the procedure provided in 42 U.S.C. § 405(g)-(h). *Heckler*, 466 U.S. at 605. The provision in question in *Heckler* actually contains the language "arise under," while the provision in question here has no such language. *Id.* at 615. Additionally, the *Heckler* decision informs remedy exhaustion analysis, and not preemption analysis.

Defendants argue that the regulations for "approval of marketing materials and enrollment forms" preempt plaintiffs' claims insofar as they relate to defendants' marketing materials. *See* 42 C.F.R. § 423.50 (2005). The regulations establish comprehensive standards for marketing materials, and they provide for a mandatory CMS approval process before those marketing materials can be used. *Id.* Included in the regulations are provisions prohibiting marketing materials that "could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan." § 423.50(f)(iv). There are clearly standards established under Medicare Part D statute with respect to marketing materials, and those standards supersede state law pursuant to the express preemption language of Part D. Thus, plaintiffs' consumer protection claims are preempted, and their fraud and fraud in the inducement claims are preempted to the extent that they rely on defendants' marketing materials.

\*3 Defendants further argue that plaintiffs seek a "coverage determination" and that their claims are therefore governed exclusively by the coverage determinations process set out in 24 C.F.R. § 423.562 et seq. According to § 423.566, a coverage determination is: 1) a decision not to provide or pay

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for a Part D drug; 2) failure to provide a coverage determination in a timely manner; 3) a decision concerning an exceptions requests under two different sections of the part; 4) a decision about the amount of cost sharing for a drug. 42 C.F.R. § 423.566(b) (2005).

Plaintiffs argue that they do not seek-or seek to appeal-a "coverage determination." They argue that they do not claim that defendants have made an incorrect decision about whether to pay for a certain drug, nor do they complain of any of the other conduct listed in the "coverage determination" definition. Instead, they claim that they were outside the system entirely because they did not have access to the order forms and instructions by which they could order prescription drugs. Defendants contend that plaintiffs' claim is, at bottom, one about failure to provide coverage. Plaintiffs' complaint alleges that defendants breached their contract when defendants "failed to provide prescription drug benefits as promised," and that defendants were unjustly enriched because defendants charged premiums but failed to provide drug benefits.

The Court agrees with defendants that plaintiffs' claims fall within the ambit of the coverage determination procedures and appeals process outlined in 24 C.F.R. § 423.562 et seq. Accordingly, the coverage determination regulations promulgated under Part D supersede plaintiffs' state contract and unjust enrichment claims, and their fraud claims to the extent that those stem from a failure to provide benefits as promised.

Even if plaintiffs were not seeking a coverage determination, their claims would nonetheless be preempted by other Part D standards. In addition to "coverage determination" appeals procedures, Part D also establishes grievance procedures. 42 C.F.R. § 423.564 (2005). The grievance procedures apply to any non-coverage-determination dispute between a PDP sponsor and its enrollees about any operations, activities, or behavior of the PDP sponsor. *See* 42 C.F.R. §§ 423.560, 423.564 (2005). The regulations require that a PDP sponsor provide "meaningful procedures for timely hearing and resolving grievances," subject to certain standards outlined by CMS. 42 C.F.R. § 423.564(a), (e)-(g). These grievance procedures cover plaintiffs' complaint that defendants failed to provide drug order forms and instructions. As a result, plaintiff's contract and unjust enrichment claims, and their fraud claims to the

extent that they relate to promises to provide forms and instructions, are preempted by the federally established grievance procedures.

Plaintiffs argue that preemption by grievance procedures leads to the "absurd" result of making PDP sponsors the "sole and final judges of any claims brought against them." However, grievances, even when adjudicated by insurance companies themselves, are not entirely inconsequential. PDP sponsors must maintain records of all grievances and their dispositions, and they must report all grievances to CMS. 42 C.F.R. § 423.564(g); Medicare Part D Reporting Requirements, CMS, Jan. 25, 2006. CMS then has the authority to impose "intermediate sanctions," including fines of up to \$100,000, on PDP sponsors for violations including misrepresentation and failure to provide medically necessary items. 42 C.F.R. §§ 423.750, 423.752 (2005).

\*4 Plaintiffs also argue that CMS's commentary indicates that Congress did not intend to preempt state contract and tort remedies. Specifically, plaintiffs cite CMS's opinion that Congress did not intend to preempt state claims for torts such as wrongful death. 70 Fed.Reg. 4362 (Jan. 28, 2005). CMS goes on to say that Congress did not intend to preempt state contract law with respect to disputes between plans and their *subcontractors*. *Id.* In short, CMS believes that "an enrollee will still have state remedies available in cases in which the legal issue before the court is independent of an issue related to the organization's status" as a PDP sponsor. *Id.* Defendants point out, however, that this action is entirely derived from defendants' provision of a Part D drug benefit, and not from its other activities as a private insurer. (Dkt. # 27 at 5). Accordingly, the plaintiffs' claims are related to the organization's status as a PDP sponsor, and Congress intended to preempt them.

Furthermore, the legislative history of the preemption provision makes it clear that Congress intended Part D preemption to be broad in scope. Prior to the MMA, state laws were preempted wherever they were "inconsistent" with federal standards, or when they related to one of four specified categories. 42 U.S.C. § 1395w-26(b)(3) (2002). The MMA, in contrast, provided that federal standards shall supersede all state laws and regulations with respect to PDP plans, except for standards relating to licensure and solvency. *See* 42 U.S.C. §§ 1395w-

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26(b)(3), 1395w-112(g) (2006). As CMS explains this change: “[t]he [old] presumption was that a state law was not preempted if it did not conflict with a [Medicare managed care] requirement and did not fall into one of the four categories where preemption was presumed ... [T]he MMA reversed this presumption and provided that state laws are *presumed to be preempted* unless they relate to licensure or solvency.” 70 Fed.Reg. 4319 (emphasis added).

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Additionally, however harsh preemption may seem to particular claimants, it is consistent with the structure and purpose of the MMA. In discerning the precise scope of express preemption, the Court may look to the statutory framework and the structure and purposes of the statute as a whole. Medtronic v. Lohr, 518 U.S. 470, 484, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). The Medicare statutes and regulations create an exceedingly complex national program which requires administration by agencies with expertise in the area. As CMS has noted when discussing the preemption provision with respect to the Medicare managed care program, “ Congress intended that the ... program, a Federal program, operate under Federal rules.” 69 Fed.Reg. 46904 (Aug. 3, 2004). Furthermore, CMS expressed its opinion that Congress broadened the scope of preemption in order to facilitate the operation of regional PDP providers. *Id.* To this end, Congress recognized that “ establishing a uniform set of grievance standards [would] reduce confusion and burden for enrollees and plans.” 70 Fed.Reg. 4362 (Jan. 28, 2005). The structure and purpose of the Medicare statutes confirm Congress's intent to preempt most state law with federal standards.

#### *D. Exhaustion of Remedies*

\*5 Because this Court finds that plaintiffs' claims are preempted for the reasons stated above, the exhaustion of remedies questions raised by the parties are moot.

#### CONCLUSION

Accordingly, the Court hereby ORDERS that:

Defendant's motion to dismiss (Dkt.# 9-1) is GRANTED in its entirety, and plaintiff's claims are DISMISSED for failure to state a claim on which relief may be granted.